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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,439	01/26/2001	Richard L. Verrier	1565.0020002	4394

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EXAMINER
LAM, ANN Y

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,439	VERRIER ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-47,49,50,55-59,61-64 and 66-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-47,49,50,55-59,61-64 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 30-36, 45-47, 49, 50, 55, 56, 61-63 and 66-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al., 5,941,869.

As to claim 30, Patterson et al. discloses a guide catheter (58); an infusion guide wire (50) coaxial with said guide catheter; and a leading guide wire (56) for entering the human heart transvenously in combination with the infusion guide wire, the leading guide wire being coaxial with said infusion guide wire and having a diameter sufficiently small to be passed through a lumen of said infusion guide wire, said leading guide wire having a sufficient length to pass through and protrude from a distal end of said infusion guide wire, and having a distal end capable of penetrating a wall of the right atrium, wherein both guide wires having sufficient flexibility for simultaneously passing

transveously through said guide catheter into the right atrium of the subject's heart via a transvenous route, see column 6, line 65 – column 7, line 9.

As to claim 31, said infusion wire has a diameter as claimed, see column 7, lines 1-6.

As to claim 32, said guide catheter has length and flexibility as claimed, see column 7, lines 1-6.

As to claim 33, said infusion guide wire has flexibility as claimed, see column 7, lines 1-6.

As to claims 34, 36, said infusion guide wire functions as an aspiration catheter and has a lumen with a diameter as claimed, see column 7, lines 6-9.

As to claim 35, said leading guide wire has flexibility as claimed, see column 7, lines 1-6.

As to claim 45, the leading guide wire is steerable to any location within the pericardium, see column 7, lines 1-6.

As to claim 46, the kit is adapted to perform a surgical procedure on the heart, see column 7, lines 1-6.

As to claim 47, the kit is adapted for placing an implantable device into the pericardium, see column 7, lines 6-9.

As to claims 49, 66-70, the infusion guide wire and leading guide wire jointly have the pushability as claimed, see column 7, lines 1-6.

As to claims 50, 61, 62, the infusion guide wire has a lumen with a diameter as claimed, see column 7, lines 1-6.

As to claims 55, 56,the dual guide wire has flexibility without kinking as claimed, see column 7, lines 1-6.

As to claim 63, said infusion guide wire is coaxial with the guide catheter as claimed, see Figure 1, and column 12, line 56 – column 13, line 12.

As to claim 71, the dual guide wire is adapted for implantation as claimed, see column 12, line 56 – column 13, line 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869.

Patterson et al. discloses the invention substantially as claimed, except for the leading guide wire having a diameter as claimed. However, it would have been obvious to one of ordinary skill in the art to provide a leading guide wire having the claimed diameter as would be necessary to perform a surgical procedure on a patient having an anatomical passageway of a particular size,

3. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869, in view of Helmus et al., 5,569,197.

Patterson et al. discloses the invention substantially as claimed, see above, except for the leading guidewire being hollow.

Helmus et al. teaches a hollow guidewire (20) for drug delivery, see column 4, lines 18-29. Helmus et al. also teaches that the hollow guidewire may be used with a catheter, see column 2, lines 55-65. It would have been obvious to use a hollow guidewire as taught by Helmus et al. with the Patterson et al. catheter and sheath in order to guide the catheter and sheath and to deliver drugs, as taught by Helmus et al..

4. Claims 42-44, 57-59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al., 5,941,869, in view of Mottola et al. 5,957,901.

Patterson et al. discloses the invention substantially as claimed, see above, except for a radiopaque marker as claimed.

Mottola et al. discloses a catheter with a radiopaque marker in order to provide the user with means for positioning the device at a desired location, see column 4, lines 4-7. It would have been obvious to provide a radiopaque marker on the Patterson et al. catheter, infusion guidewire or leading guidewire, in order to provide means for positioning the device, as taught by Mottola et al.

Response to Arguments

Applicant's arguments filed June 24, 2003 have been fully considered but they are not persuasive. Applicant argues that the amended claims use functional language, rather than the alleged intended-use language, see top of page 8 of Applicant's response. Examiner however asserts that the functional language is examined in the

same way as intended-use language. Thus, a recitation of the intended use (or functional language) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use (or claimed function), then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant also argues that the amended claims now recite that the infusion guide wire and the leading guide wire together have sufficient flexibility "for simultaneously passing transvenously through the guide catheter into the right atrium," see top of page 8 of Applicant's response. Applicant further argues that the catheter of Paterson et al. is not designed for transvenous use, rather than for use in veins, which tend to be much more delicate than arteries. In response, Examiner asserts that the infusion guide wire and the leading guide wire together have the claimed flexibility. Patterson et al. teaches use of the catheter in veins as well as arteries, see for example column 25, lines 29-31, and lines 37-38.

Applicant also argues that the Patterson et al. catheter is not designed for entry into the heart, see page 8. In response, Examiner asserts that the catheter is capable of entering the heart. Applicant's recitation of the intended use (or functional languge) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
09/19/05